DOCKET NO.: 246080US0CONT

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COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

RE: Application Serial No.: 10/724,179
Applicants: Katsutoshi SAKATA et al
Filing Date: December 1, 2003
For: DIHYDRODIARYLOXAZEPINE DERIVATIVE AND PHARMACEUTICAL COMPOSITION CONTAINING THE SAME
Group Art Unit: 1624
Examiner: COLEMAN, B. L.

SIR:

Attached hereto for filing are the following papers:

REQUEST FOR EXTENSION OF TIME (ONE MONTH); REQUEST FOR RECONSIDERATION; ENGLISH TRANSLATION OF WRITTEN OPINION FOR PCT/JP02/05193; ENGLISH TRANSLATION OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT FOR PCT/JP02/05193

Our credit card payment form in the amount of $120.00 is attached covering any required fees. In the event any variance exists between the amount enclosed and the Patent Office charges for filing the above-noted documents, including any fees required under 37 C.F.R §1.136 for any necessary Extension of Time to make the filing of the attached documents timely, please charge or credit the difference to our Deposit Account No. 15-0030. Further, if these papers are not considered timely filed, then a petition is hereby made under 37 C.F.R. §1.136 for the necessary extension of time. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.

Stephen G. Baxter
Registration No. 32,884

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PATENT COOPERATION TRATY

From the Japanese Patent Office
Internaitonal Preliminary Examination Authority

P C T

WRITTEN OPINION
(PCT Rule 66)

To: Minoru NAKAMURA Address: Room 646, Shin-Tokyo Bldg., No. 3-1 Marunouchi 3-Chome, Chiyoda-ku Tokyo 100 JAPAN	Date of Mailing: February 4, 2003
Applicant's or agent's file ref. Y1J0369	REPLY DUE within 2 months from the above date of mailing
International Appln. No. PCT/JP02/05193	International filing date (day/month/year) 29/05/2002
	Priority date (day/month/year) 30/05/2001
International Patent Classification(IPC)or both national classification and IPC Int. Cl[7] C07D267/18,413/04,413/06,413/14,A61K31/553,A61P1/00	
Applicant AJINOMOTO CO., INC.	

1. This written opinion is the first (first, ect.)drawn by this International Preliminary Examination Authority.

2. This opinion contains indications relating to the following items:
   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step or industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.
   - When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension.
   - How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3.
     For the form and the language of the amendments, see Rules 66.8 and 66.9.
   - Also For an additional opportunity to submit amndments, see Rule 66.4
     For the examiner's obligation to consider amendments and/or arguments see Rule 66.4 bis.
     For an informal communication with the examiner, see Rule 66.6

   If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is September 30, 2003

Name and mailing address JAPANESE PATENT OFFICE(IPEA/JP) 4-3, Kasumigaseki 3-Chome, Chiyoda-ku, Tokyo, 100, JAPAN	Authorized officer 4C3127 Koji ITO Telephone No. 03-3581-1101 Ex. 3451

WRITTEN OPINION | International Application No. PCT/JP 02 / 05193

I . Basis of the Opinion

1. This opinion has been drawn on the basis of;

[X] the international application as originally filed

[ ] the description:

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

[ ] the claims:

pages _____, as originally filed

pages _____, as amended (together with any statement under Article 19

pages _____, filed with the demand

pages _____, filed with the letter of _____

[ ] the drawings:

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

[ ] the sequence listing part of the description:

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the Written Opinion was carried out on the basis of the sequence listing:

[ ] contained in the international application in written form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. [ ] The amendments have resulted in the cancellation of:

[ ] the description, pages _____

[ ] the claims, Nos. _____

[ ] the drawings, sheets/fig _____

5. [ ] This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

WRITTEN OPINION | International Application No. PCT/JP 02 / 05193

V . Reasoned statement under Article 35(2) with regard to novelty, inventive step or indusrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty(N)	Claims 3,5,13,15,16,34-37	YES
	Claims 1,2,4,6-12,14,17-33	NO
Inventive Step (IS)	Claims 3,5	YES
	Claims 1,2,4,6-37	NO
Industrial Applicability(IA)	Claims 1-37	YES
	Claims	NO

2. CITATIONS AND EXPLANATIONS

Please see attached paper.

2. Cited references and explanation

Reference 1: WO 00/40570 A1 (AJINOMOTO CO., INC)
2000.07.13
Reference 2: EP 1020466 A1 (AJINOMOTO CO., INC)
2000.07.19
Reference 1: EP 889043 A1 (AJINOMOTO CO., INC)
1999.01.07
Reference 1: WO 01/17980 A1 (AJINOMOTO CO., INC)
2001.03.15

Regarding claims 1, 2, 4, 6-12, 14, 17-25

The inventions of claims 1, 2, 4, 6-12, 14, 17-25 are not novel and do not involve an inventive step in light of references 1 to 4 cited in the international search report.
The cited references 1 to 4 disclose 5,11-dihydrodibenzo[b,e][1,4]oxazepine derivatives which are useful in treating or preventing functional gastrointestinal disorders, and which correspond to the compounds represented by the general formula [I] set out in claim 1 of the present application (see Reference 1: Examples 1-2; Reference 2: Examples 1-40; Reference 3: Example 1-22; Reference 4: compound (6)).

Regarding claims 13, 15 and 16

The inventions of claims 13, 15 and 16 do not involve an inventive step in light of references 1 to 4 cited in the international search report.
It is easy for those skilled in the art to replace a certain substituent among the substituents of 5,11-dihydrodibenzo[b,e][1,4]oxazepine derivatives with a similar substituent to provide compounds having functions similar to those of the 5,11-dihydrodibenzo[b,e][1,4]oxazepine derivatives.
In this connection, the present specification does not show the fact that, based on the difference in certain substituent, the compounds

of claims 13, 15 and 16 produce superior effects to those produced by the compounds disclosed in the cited references, and therefore, it is not admitted that the effects produced by the inventions of claims 13, 15 and 16 are un-expected and excellent in such that those skilled in the art cannot predict from the prior art.

Regarding claims 26-33

The inventions of claims 26-33 are not novel and do not involve an inventive step in light of reference 4 cited in the international search report.
Reference 4 discloses compounds (1) and (2) which are intermediates to synthesize 5,11-dihydrodibenzo[b,e][1,4]oxazepine derivatives useful for the treatment or prevention of functional gastrointestinal disorders.

Regarding claims 34-37

The inventions of claims 34-37 do not involve an inventive step in light of reference 4 cited in the international search report.
Reference 4 discloses compounds (1) and (2) which are intermediates to synthesize 5,11-dihydrodibenzo[b,e][1,4]oxazepine derivatives useful for the treatment or prevention of functional gastrointestinal disorders.
On the other hand, the inventions of claims 34-37 are directed to synthetic intermediates for 5,11-dihydrodibenzo[b,e][1,4]oxazepine derivatives having similar chemical structures to those of the compounds of Reference 4. Therefore, it is easy for those skilled in the art to replace certain substituent among the substituents of intermediate compounds (1) and (2) with a similar substituent in order to prepare 5,11-dihydrodibenzo[b,e][1,4]oxazepine derivatives having similar chemical structures to those of the compounds of Reference 4.

Regarding claims 3, 5

The inventions of claims 3 and 5 are novel and involve an inventive step since the inventions are not discloses in any references cited in the international search report.
In particular, compounds wherein either one of rings G and J in the general formula (1) of the present application is a pyridine ring, and compounds wherein a ring K in the general formula (1) is any one of pyridine ring, pyrimidine ring, pyrazine ring and pyridazine ring are not disclosed in the references 1 to 4 which are considered to be the most pertinent to the present invention.

PATENT COOPERATION TREATY

From Japanese Patent Office
(The International Preliminary Examining Authority)

To : Minoru NAKAMURA
Address: Room 646,
Shin-Tokyo Bldg., 3-1,
Marunouchi 3-Chome,
Chiyoda-Ku, Tokyo, 100

PCT

NOTIFICATION OF TRANSMITTAL OF THE
INTERNATIONAL PRELIMINARY EXAMINATION REPORT
[Enforcement Regulation 57]
[PCT Rule 71.1]

Date of Mailing May 27, 2003

Applicant's or Agent's file reference
Y1J0369

IMPORTANT NOTIFICATION

International Filing Number	International Filing Date	Priority Date
PCT/JP 02/05193	May 29, 2002	May 30, 2001

Applicant AJINOMOTO CO., INC.

1. The applicant is hereby notified that the International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, eatablished on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Office) (Article 39(1)) (See also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and address:
Japanese Patent Office (IPEA/JP)
No. 4-3, Kasumigaseki 3-chome,
Chiyoda-ku, Tokyo, 100 JAPAN

Competent Officer 4C 3127
Authorized Official
Commisioner of the Patent Office
Telephone No. : 03-3581-1101 Ex. 3451

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference Y1J0369	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/JP02/05193	International filing date (*day/month/year*) May 29, 2002	Priority date (*day/month/year*) May 30, 2001
International Patent Classification (IPC) or national classification and IPC Int. Cl[7] C07D267/18,413/04,413/06,413/14,A61K31/553,A61P1/00		
Applicant AJINOMOTO CO., INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand November 15, 2002	Date of completion of this report May 8, 2003
Name and mailing address of the IPEA/JP JAPAN PATENT OFFICE Facsimile No.	Authorized officer Koji ITO 4C3127 Telephone No. 03-3581-1101 Ex: 3451

Form PCT/IPEA/409 (cover sheet) (July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP02/05193

I. Basis of the report

1. With regard to the elements of the international application:*

[X] the international application as originally filed.

[ ] the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

[ ] the claims:

pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

[ ] the drawings:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

[ ] the sequence listing part of the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
[ ] the language of publication of the international application (under Rule 48.3(b)).
[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

[ ] contained in the international application in written form.
[ ] filed together with the international application in computer readable form.
[ ] furnished subsequently to this Authority in written form.
[ ] furnished subsequently to this Authority in computer readable form.
[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
[ ] The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

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[ ] the description, pages _____
[ ] the claims, Nos. _____
[ ] the drawings, sheets/fig _____

5. [ ] This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP02/05193

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	3,5,13,15,16,34-37	YES
	Claims	1,2,4,6-12,14,17-33	NO
Inventive step (IS)	Claims	3,5	YES
	Claims	1,2,4,6-37	NO
Industrial applicability (IA)	Claims	1-37	YES
	Claims		NO

2. Citations and explanations

Please see attached paper.

2. Cited references and explanation

Reference 1: WO 00/40570 A1 (AJINOMOTO CO., INC)
2000.07.13
Reference 2: EP 1020466 A1 (AJINOMOTO CO., INC)
2000.07.19
Reference 1: EP 889043 A1 (AJINOMOTO CO., INC)
1999.01.07
Reference 1: WO 01/17980 A1 (AJINOMOTO CO., INC)
2001.03.15

Regarding claims 1, 2, 4, 6-12, 14, 17-25

The inventions of claims 1, 2, 4, 6-12, 14, 17-25 are not novel and do not involve an inventive step in light of references 1 to 4 cited in the international search report.
The cited references 1 to 4 disclose 5,11-dihydrodibenzo[b,e][1,4]oxazepine derivatives which are useful in treating or preventing functional gastrointestinal disorders, and which correspond to the compounds represented by the general formula [I] set out in claim 1 of the present application (see Reference 1: Examples 1-2; Reference 2: Examples 1-40; Reference 3: Example 1-22; Reference 4: compound (6)).

Regarding claims 13, 15 and 16

The inventions of claims 13, 15 and 16 do not involve an inventive step in light of references 1 to 4 cited in the international search report.
It is easy for those skilled in the art to replace a certain substituent among the substituents of 5,11-dihydrodibenzo[b,e][1,4]oxazepine derivatives with a similar substituent to provide compounds having functions similar to those of the 5,11-dihydrodibenzo[b,e][1,4]oxazepine derivatives.
In this connection, the present specification does not show the fact that, based on the difference in certain substituent, the compounds

of claims 13, 15 and 16 produce superior effects to those produced by the compounds disclosed in the cited references, and therefore, it is not admitted that the effects produced by the inventions of claims 13, 15 and 16 are un-expected and excellent in such that those skilled in the art cannot predict from the prior art.

Regarding claims 26-33

The inventions of claims 26-33 are not novel and do not involve an inventive step in light of reference 4 cited in the international search report.
Reference 4 discloses compounds (1) and (2) which are intermediates to synthesize 5,11-dihydrodibenzo[b,e][1,4]oxazepine derivatives useful for the treatment or prevention of functional gastrointestinal disorders.

Regarding claims 34-37

The inventions of claims 34-37 do not involve an inventive step in light of reference 4 cited in the international search report.
Reference 4 discloses compounds (1) and (2) which are intermediates to synthesize 5,11-dihydrodibenzo[b,e][1,4]oxazepine derivatives useful for the treatment or prevention of functional gastrointestinal disorders.
On the other hand, the inventions of claims 34-37 are directed to synthetic intermediates for 5,11-dihydrodibenzo[b,e][1,4]oxazepine derivatives having similar chemical structures to those of the compounds of Reference 4. Therefore, it is easy for those skilled in the art to replace certain substituent among the substituents of intermediate compounds (1) and (2) with a similar substituent in order to prepare 5,11-dihydrodibenzo[b,e][1,4]oxazepine derivatives having similar chemical structures to those of the compounds of Reference 4.

Regarding claims 3, 5

The inventions of claims 3 and 5 are novel and involve an inventive step since the inventions are not discloses in any references cited in the international search report.

In particular, compounds wherein either one of rings G and J in the general formula (1) of the present application is a pyridine ring, and compounds wherein a ring K in the general formula (1) is any one of pyridine ring, pyrimidine ring, pyrazine ring and pyridazine ring are not disclosed in the references 1 to 4 which are considered to be the most pertinent to the present invention.